registration will include the details needed to participate in the web meeting. Non-US citizens are encouraged to participate in the web meeting. Non-US citizens registering to attend in person after June 2 will not have time to comply with security procedures.

Background: NORA is a partnership program to stimulate innovative research in occupational safety and health leading to improved workplace practices. Unveiled in 1996, NORA has become a research framework for the nation. Diverse parties collaborate to identify the most critical issues in workplace safety and health. Partners then work together to develop goals and objectives for addressing those needs and to move the research results into practice. The NIOSH role is facilitator of the process. For more information about NORA, see *http://www.cdc.gov/niosh/nora/about.html.*

Since 2006, NORA has been structured by industrial sectors. Eight sector groups have been defined using the North American Industrial Classification System (NAICS). After receiving public input through the web and town hall meetings, NORA Sector Councils have been working to define sector-specific strategic plans for conducting research and moving the results into widespread practice. During 2008, most of these Councils will post draft strategic plans for public comment. For more information, see the link above and choose "Sector-based Approach," "NORA Sector Councils" and "Comment on Draft Sector Agendas" from the right-side menu.

Contact Person for Technical Information: Sidney C. Soderholm, PhD, NORA Coordinator, e-mail *noracoordinator@cdc.gov*, telephone (202) 245–0665.

Dated: May 5, 2008.

James D. Seligman,

Chief Information Officer, Centers for Disease Control and Prevention.

[FR Doc. E8–10753 Filed 5–13–08; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Delegation of Authority

Notice is hereby given that I have redelegated to Charles N.W. Keckler, Esq., Senior Advisor, Immediate Office of the Assistant Secretary, Administration for Children and Families (ACF), the following authority vested in the Assistant Secretary for Children and Families.

(a) Authority Delegated.

Authority to review and make decisions to approve or disapprove requests for testimony by ACF employees or former ACF employees concerning information acquired in the course of performing official duties or because of such persons' official capacity with the Department of Health and Human Services in proceedings where the United States is not a party.

(b) Limitations and Conditions.

This redelegation may not be further redelegated.

(c) Effect on Existing Delegations.

None.

(d) Effective date.

This redelegation is effective on the date of signature. I hereby affirm and ratify any actions taken by Mr. Charles Keckler which, in effect, involved the exercise of this authority prior to the effective date of this redelegation.

Dated: May 2, 2008.

Daniel C. Schneider,

Acting Assistant Secretary for Children and Families.

[FR Doc. E8–10766 Filed 5–13–08; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–E–0102] (formerly Docket No. 2007E–0184)

Determination of Regulatory Review Period for Purposes of Patent Extension; AVASTIN

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for AVASTIN and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human biological product.

ADDRESSES: Submit written or electronic comments and petitions to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6222, Silver Spring, MD 20993–0002, 301–796–3602.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human biological products, the testing phase begins when the exemption to permit the clinical investigations of the biological becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human biological product and continues until FDA grants permission to market the biological product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human biological product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA approved for marketing the human biologic product AVASTIN (bevacizumab). AVASTIN, used in combination with intravenous 5-fluorouracil-based chemotherapy, is indicated for first-line treatment of patients with metastatic carcinoma of the colon or rectum. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for AVASTIN (U.S. Patent No. 6,639,055) from Genentech, Inc., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated July 24, 2007, FDA advised the Patent and Trademark Office that this human biological product had undergone a regulatory review period and that the approval of AVASTIN represented the

first permitted commercial marketing or use of the product. Thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for AVASTIN is 2,551 days. Of this time, 2,401 days occurred during the testing phase of the regulatory review period, while 150 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) became effective*: March 5, 1997. The applicant claims February 3, 1997, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was March 5, 1997, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human biological product under section 351 of the Public Health Service Act (42 U.S.C. 262)*: September 30, 2003. The applicant claims August 29, 2003, as the date the biologics license application (BLA) for AVASTIN (BLA 125085/0) was initially submitted. The applicant claims this is the date it submitted the first unit of BLA 125085/0, which was submitted in several units as part of a rolling application procedure. It is FDA's position that the approval phase begins when the marketing application is complete. A review of FDA records reveals that the final module of the BLA 125085/0 was submitted on September 30, 2003, which is considered to be the date the complete marketing application was initially submitted.

3. *The date the application was approved*: February 26, 2004. FDA has verified the applicant's claim that BLA 125085/0 was approved on February 26, 2004.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 121 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments and ask for a redetermination by July 14, 2008. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by November 10, 2008. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Division of Dockets Management. Three copies of any mailed information are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that on January 15, 2008, the FDA Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic submissions will be accepted by FDA through FDMS only.

Dated: April 28, 2008.

Jane A. Axelrad,

Associate Director for Policy, Center for Drug Evaluation and Research.

[FR Doc. E8–10726 Filed 5–13–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–E–0399] (formerly Docket No. 2007E–0145)

Determination of Regulatory Review Period for Purposes of Patent Extension; INVEGA

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for INVEGA and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

ADDRESSES: Submit written comments and petitions to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6222, Silver Spring, MD 20993–0002, 301–796–3602.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the human drug product becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product INVEGA (paliperidone). INVEGA is indicated for the treatment of schizophrenia. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for INVEGA (U.S. Patent No. 5,158,952) from Janssen, L.P., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated July 23, 2007, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of INVEGA represented the first permitted commercial marketing or use of the product. Thereafter, the Patent and